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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
DUNSTON, JENNIFER ANN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,283	DERAND ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,13-16,18 and 24-46* is/are pending in the application.

4a) Of the above claim(s) *4-10,14,16,18,26-33 and 36-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,13,15,24,34,35,45 and 46* is/are rejected.

7)☒ Claim(s) *25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment, filed 10/7/2005, in which claims 2, 11-12, 17 and 19-23 were canceled; and claims 1, 3, 13, 24, 25, 34, 45 and 46 were amended. Applicants' arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn.

This action is FINAL.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant elected Group I (claims 1-29, 34, 35, 45 and 46) in the reply filed on 2/10/2005. Applicant also elected sub-species type (a) spacer, sub-species type (b) MRP1, and sub-species type (c) Kir6.2.

Claims 4-10, 14, 16, 18 and 26-29 and the sequences of SEQ ID NOS: 2, 3, 5, 7 and 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/10/2005.

This application contains claims (30-33 and 36-44) drawn to an invention nonelected with traverse in the reply filed 2/10/2005.

Response to Arguments - Claim Objections

Applicant's arguments, see page 11, filed 10/7/2005, with respect to the previous objection of claims 45 and 46 have been fully considered and are persuasive. The objection of claims 45 and 46 has been withdrawn.

Applicant's arguments filed 10/7/2005 have been fully considered but they are not persuasive. The response asserts that claim 25 should be examined as it reads on other nonelected species, upon an indication of allowability for the claim as it encompasses the elected species. This is not found persuasive because the generic claim has not been found allowable. Thus, the claims remain restricted to the elected species (see page 4 of the Office action mailed 11/2/2004).

Claim Objections

Claim 25 is objected to because of the following informalities: the claim reads on non-elected species. This objection was made in the Office action mailed 4/7/2005.

Response to Amendment

The declaration under 37 CFR 1.132 filed 10/7/2005 is sufficient to overcome the rejection of claim 25 based upon insufficiency of disclosure under 35 U.S.C. 112, first paragraph (enablement). The declaration provides evidence that a hybrid protein of MDR1 and Kir6.2 is able to function as an electrical sensor in that it is expressed, properly folded, trafficked and inserted into the membrane, such that a functional channel is formed (e.g. page 2 and Figures 1 and 2 of the declaration). The addition of the HA tag does not materially affect the novel

characteristics of the hybrid protein (e.g. Figure 1).

The declaration under 37 CFR 1.132 filed 10/7/2005 is insufficient to overcome the rejection of claims 1-3, 11-13 15, 21-24, 34, 35, 45 and 46 based upon 35 USC 112, first paragraph, for failing to comply with the written description requirement as set forth in the last Office action because the showing is not commensurate in scope with the claims. The declaration does not set forth the combinations of ABC transporter proteins and Kir family proteins that are naturally coupled, such that one could select combinations that are not naturally coupled.

Response to Arguments - 35 USC § 112

Applicant's arguments, see pages 11-16, filed 10/7/2005, with respect to the rejection of claim 25 based upon insufficiency of disclosure under 35 U.S.C. 112, first paragraph (enablement) have been fully considered and are persuasive.

Applicant's arguments filed 10/7/2005 have been fully considered but they are not persuasive with regard to the rejection of claims 1-3, 11-13, 15, 21-24, 34, 35, 45 and 46 as failing to comply with the written description requirement and the rejection of claims 1-3, 11-13, 15, 21-24, 34, 35, 45 and 46 as failing to comply with the enablement requirement. Amended claim 1 is drawn to a hybrid protein consisting essentially of an ABC transporter membrane protein, a spacer, and an ATP-sensitive potassium ion channel from the Kir family, which is not naturally coupled to said ABC transporter membrane protein, wherein said membrane protein, spacer, and potassium channel are functionally coupled so that ligand binding to the ABC

transporter membrane protein transduces a signal to the potassium channel that produces an electrical signal. The declaration provides evidence that an MRP1-Kir6.2 hybrid protein is operable in the context of the claimed invention. The MRP1-Kir6.2 hybrid protein (e.g. SEQ ID NO: 1) is a species of the claimed genus. Further, the response points to the specification as evidence that the inventors could make and express fusion proteins of ABC transporters (MRP1, YCF1, and MDR1, for example) and Kir6.2 protein (e.g. pages 14-15 of the response). Other documents provided in the response provide evidence that the structure of Kir channels is conserved (Heinemann, for example) (e.g. page 15 of the response). Given that the nucleic acid sequences of ABC transporters and Kir ion channels are known, one of skill in the art could make the hybrid proteins of claim 1 and determine if the obtained hybrid protein is capable of functioning as a biosensor based upon the teachings of the instant specification.

The response asserts that the invention as now claimed is clearly directed to specific, well-known classes of membrane and ion channel proteins: nucleic acid sequences encoding ABC transporters, nucleic acid sequences encoding Kir6.2 or a derivative thereof (page 16 of the response). Further, the response asserts that the arrangement of these elements into functional hybrid proteins is within the skill of the art. This is not found persuasive because the claims are drawn to hybrid proteins consisting essentially of any ABC transporter protein and any Kir family potassium channel that is not naturally coupled to the ABC transporter protein. Further, the claims encompass combinations of any ABC transporter and any Kir family potassium channel. As stated on page 7 of the prior Office action, "No description is provided of the genus of membrane proteins that are normally coupled with ion channels. A representative number of species of membrane proteins that are normally coupled with ion channels are not disclosed, and

no structural/functional relationship is provided to allow one of skill in the art to envision a representative number of members of this genus." The response has not provided evidence that one could make and use the claimed hybrid protein or that applicant's were in possession of the claimed hybrid protein, where the ABC transporter and Kir family potassium channel are selected from proteins not naturally coupled.

For these reasons, and the reasons made of record in the previous office actions, the rejections are maintained.

Claim Rejections - 35 USC § 112

Claims 1, 3, 13, 15, 24, 34, 35, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a hybrid protein consisting essentially of an MRP1 membrane proteins, a spacer, and a Kir6.2 potassium channel, wherein said spacer is between said MRP2 membrane protein and said Kir6.2 potassium channel does not reasonably provide enablement for a hybrid protein comprising an ATP-sensitive potassium ion channel from the Kir family which is not naturally coupled to and ABC transporter membrane protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The grounds of this rejection have been changed in response to Applicants' amendment of the claims in the response filed on 10/7/2005.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of

experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The claims are drawn to a hybrid protein consisting essentially of an ABC transporter membrane protein, a spacer, and an ATP-sensitive potassium ion channel from the Kir family, which is not naturally coupled to said ABC transporter membrane protein, wherein said spacer is between said ABC transporter membrane protein and said ATP-sensitive potassium channel. Claim 13 limits the ABC transporter membrane protein to an ABC transporter from the MRP class. The MRP class protein may be coupled to any Kir protein not naturally coupled to the MRP class. Claim 24 limits the ATP-sensitive potassium channel to Kir6.2. The Kir6.2 protein may be coupled to any ABC transporter protein not naturally coupled to Kir6.2. The nature of the invention is complex in that one must know which ABC transporters are naturally coupled to which Kir family proteins.

Breadth of the claims: The claims are broad in scope in that any ABC transporter may be coupled to any Kir family protein. Based upon the underdeveloped and unpredictable nature of the invention (discussed below), the degree to which the phrase "not naturally coupled" limits the scope of the invention.

Guidance of the specification and existence of working examples: The specification envisions the use of the hybrid proteins as electrical sensors of membrane protein (e.g. receptor or transporter) activity such that the receptor or transporter occupancy by a ligand is transferred to the ion channel and transduced into an electrical signal that is detected by standard electrophysiological techniques (e.g. page 1, lines 3-13; page 3, lines 1-5). The specification envisions the use of membrane proteins such as receptors, active transporters and passive

transporters such as neurotransmitter receptors, hormone receptors, drug receptors, olfactive receptor, and heavy metal transporters (e.g. page 3, lines 24-28). Regarding the ion channel, the specification envisions the use of channels which have one or several of the following properties: they are coupled with a receptor/transporter in a physiological manner, they are encoded by a very small gene and easily handled by molecular biology, their gating behavior is straightforward and they are regulated and blocked by a simple ligand, which allows testing of the hybrid protein by simple electrophysiological assays (e.g. page 4, lines 1-7). The specification teaches how to make the following hybrid proteins, which meet the structural limitations of the claims: MRP1-Kir6.2, YCF1-Kir6.2, MRP1-Kir6.2ΔC36, YCF1-Kir6.2ΔC36, MRP1-Kir6.2[KR370AA], MRP1-Kir6.2HA, YCF1-Kir6.2ΔC36HA, YCF1-Kir6.2ΔC36HA-FCYENE, and Mdr1-Kir6.2 (e.g. page 6, lines 18-25; Table 1; Example 1).

The specification provides little or no guidance with regard to the combinations of ABC transporter proteins and Kir family proteins that are naturally coupled.

Predictability and state of the art: In order to combine proteins that are not naturally coupled to make the claimed hybrid protein, one must be able to identify all the proteins that are naturally coupled. The prior art teaches that the full range of inward rectifiers that SUR1 will partner with has not been established (Aguilar-Bryan et al. Endocrine Reviews, Vol. 20, No. 2, pages 101-135, 1999; e.g. page 112, The question of "promiscuous coupling" of SUR1 with other inward rectifiers). Chan et al (EMBO J. Vol. 22, No. 15, pp. 3833-43, 2003) teach that the TMD0 domain of SUR1 strongly associates with Kir6.2 and plays an important role in its trafficking and gating (e.g. page 3834, right column). Further, Chan et al teach that TMD0 is

only found in certain members of the family of ABC proteins, including MRP1-3, MRP6-7 and SUR (e.g. page 3839, right column, 1st full paragraph). Chan et al state the following:

> The funciton of TMD0 in any of these ABC proteins is not clear. Our finding demonstrates unambiguously a direct functional role for TMD0 of an ABC protein, and raises the interesting possibility that, during evolusion, some ABC proteins might have acquired TMD0 as an extra domain to serve a supecialized purpose, such as regulating the funciton of a potassium channe. It is possible that TMD0s of other ABC proteins alos associate with membrane proteins and modulate their funciton. See page 3839, right column.

Moreover, there have been conflicting reports in the literature with regard to the combination of ABC transporter proteins and Kir family potassium channels that are naturally coupled (e.g. Aguilar-Bryan et al. Endocrine Reviews, Vol. 20, No. 2, pages 101-135, 1999; e.g. page 112, The question of "promiscuous coupling" of SUR1 with other inward rectifiers; Konstas et al. The Journal of Biological Chemistry, Vol. 277, No. 24, pages 21346-21351, 2002; Ruknudin et al. The Journal of Biological Chemistry, Vol. 273, No. 23, pages 14165-14171, 1998). Thus, all of the naturally occurring combinations of ABC transporter proteins and Kir family potassium channels have not been taught in the prior art.

Amount of experimentation necessary: The quantity of experimentation required to carry out the claimed invention is very large, as the skilled artisan could not rely upon the prior art or instant specification to select combinations of ABC transporter proteins and Kir family potassium channels that are not naturally coupled. One would have to perform exhaustive studies to test all possible combinations of ABC transporters and Kir family proteins.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an

undue amount of experimentation to make and/or use the claimed invention. Therefore, claims 1, 3, 13, 15, 24, 34, 35, 45 and 46 are not considered to be fully enabled by the instant specification.

Claims 1, 3, 13, 15, 24, 34, 35, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The grounds of this rejection have been changed in response to Applicants' amendment of the claims in the response filed on 10/7/2005.

The claims are drawn to a hybrid protein consisting essentially of an ABC transporter membrane protein, a spacer, and an ATP-sensitive potassium ion channel from the Kir family, which is not naturally coupled to said ABC transporter membrane protein, wherein said spacer is between said ABC transporter membrane protein and said ATP-sensitive potassium channel. Claim 13 limits the ABC transporter membrane protein to an ABC transporter from the MRP class. The MRP class protein may be coupled to any Kir protein not naturally coupled to the MRP class. Claim 24 limits the ATP-sensitive potassium channel to Kir6.2. The Kir6.2 protein may be coupled to any ABC transporter protein not naturally coupled to Kir6.2. Thus, the claims require a description of all naturally occurring combinations of ABC transporter proteins and Kir family potassium channels.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus.

The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification envisions the use of the hybrid proteins as electrical sensors of membrane protein (e.g. receptor or transporter) activity such that the receptor or transporter occupancy by a ligand is transferred to the ion channel and transduced into an electrical signal that is detected by standard electrophysiological techniques (e.g. page 1, lines 3-13; page 3, lines 1-5). The specification envisions the use of membrane proteins such as receptors, active transporters and passive transporters such as neurotransmitter receptors, hormone receptors, drug receptors, olfactive receptor, and heavy metal transporters (e.g. page 3, lines 24-28). Regarding the ion channel, the specification envisions the use of channels which have one or several of the following properties: they are coupled with a receptor/transporter in a physiological manner, they are encoded by a very small gene and easily handled by molecular biology, their gating behavior is straightforward and they are regulated and blocked by a simple ligand, which allows testing of the hybrid protein by simple electrophysiological assays (e.g. page 4, lines 1-7). Furthermore, the specification envisions the use of functional derivatives of membrane proteins and ion channels (e.g. pages 4-5). The specification describes fusions of the Kir6.2 ion channel to the following ABC transporter proteins not normally associated with Kir6.2: MRP1, YCF1, and Mdr1 (e.g. Table 1). No description is provided of the fusion of any other ion channel with any other membrane proteins. No description is provided of the genus of membrane proteins that are normally coupled with ion channels. A representative number of species of membrane proteins that are normally coupled with ion channels are not disclosed, and no structural/functional relationship is provided to allow one of skill in the art to envision a

representative number of members of this genus. No description is provided of the genus of ion channel proteins that are normally coupled with membrane proteins. A representative number of species of ion channels are not disclosed, and no structural/functional relationship is provided to allow one of skill in the art to envision a representative number of members of this genus.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of a few hybrid proteins. The results are not necessarily predictive of other hybrid proteins comprising an ABC transporter and a Kir family potassium channel that are not naturally coupled. Thus, it is impossible for one to extrapolate from the few examples described herein those hybrid proteins that would necessarily meet the structural/functional characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification in that the art of record does not describe a set of hybrid proteins that provide sufficient structural/functional information for one of skill in the art to envision other members of the genus. In order to combine proteins that are not naturally coupled to make the claimed hybrid protein, one must be able to identify all the proteins that are naturally coupled. The prior art teaches that the full range of inward rectifiers that SUR1 will partner with has not been established (Aguilar-Bryan et al. Endocrine Reviews, Vol. 20, No. 2, pages 101-135, 1999; e.g. page 112, The question of "promiscuous coupling" of SUR1 with other inward rectifiers). Chan et al (EMBO J. Vol. 22, No. 15, pp. 3833-43, 2003) teach that the TMD0 domain of SUR1 strongly associates with Kir6.2 and plays an important role in its trafficking and gating (e.g. page 3834, right column). Further, Chan et al teach that TMD0 is only found in certain members of

the family of ABC proteins, including MRP1-3, MRP6-7 and SUR (e.g. page 3839, right column, 1st full paragraph). Chan et al state the following:

> The funciton of TMD0 in any of these ABC proteins is not clear. Our finding demonstrates unambiguously a direct functional role for TMD0 of an ABC protein, and raises the interesting possibility that, during evolusion, some ABC proteins might have acquired TMD0 as an extra domain to serve a supecialized purpose, such as regulating the funciton of a potassium channe. It is possible that TMD0s of other ABC proteins alos associate with membrane proteins and modulate their funciton. See page 3839, right column.

Moreover, there have been conflicting reports in the literature with regard to the combination of ABC transporter proteins and Kir family potassium channels that are naturally coupled (e.g. Aguilar-Bryan et al. Endocrine Reviews, Vol. 20, No. 2, pages 101-135, 1999; e.g. page 112, The question of "promiscuous coupling" of SUR1 with other inward rectifiers; Konstas et al. The Journal of Biological Chemistry, Vol. 277, No. 24, pages 21346-21351, 2002; Ruknudin et al. The Journal of Biological Chemistry, Vol. 273, No. 23, pages 14165-14171, 1998). Thus, all of the naturally occurring combinations of ABC transporter proteins and Kir family potassium channels have not been taught in the prior art.

Given the very large genus of hybrid proteins encompassed by the rejected claims, and given the limited description provided by the prior art and specification, the skilled artisan would not have been able to envision a sufficient number of specific embodiments that meet the limitations of the claims to describe the broadly claimed genus. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those functional hybrid proteins that satisfy the limitations of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 1, 3, 13, 15, 24, 34, 35, 45 and 46.

Response to Arguments - 35 USC § 102

The rejection of claims 1, 11, 12, 34 and 35 under 35 U.S.C. 102(b) as being anticipated by Vankeerberghen et al has been withdrawn in view of Applicant's amendment.

The rejection of claims 1, 21-24, 34 and 35 under 35 U.S.C. 102(b) as being anticipated by Takano et al has been withdrawn in view of Applicant's amendment.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

jad

CELIAN QIAN
PATENT EXAMINER